

**NOT FOR PUBLICATION**

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

In re *Ex Parte* Application of SANDOZ  
CANADA, INC. for an Order to Conduct  
Discovery for Use in Foreign Proceedings  
Pursuant to 28 U.S.C. § 1782

Civil Action No. 20-02425 (MAS) (DEA)

**MEMORANDUM OPINION**

**SHIPP, District Judge**

This matter comes before the Court upon an *ex parte* Application by Petitioner Sandoz Canada, Inc. (“Petitioner” or “Sandoz”) for leave to serve a subpoena against Ronald Vladyka (“Vladyka”) pursuant to 28 U.S.C. § 1782. (ECF No. 1.) The Court has carefully considered the Petitioner’s submission and decides the matter without oral argument pursuant to Local Civil Rule 78.1. For the reasons set forth below, Petitioner’s Application is granted.

**I. BACKGROUND**

According to Petitioner’s Application, Hoffmann-La Roche Limited and InterMune, Inc. (collectively, “Roche”) and Sandoz are engaged in several patent litigations in the Federal Court of Canada. (Pet’r’s Mem. of Law 1, ECF No. 1-1.) The Patents in Issue are 2,620,380 (“’380 Patent”) and 2,762,013 (“’013 Patent”). (*Id.*) “Each of the Patents in Issue name three inventors: Ronald Vladyka, Ramachandran Radhakrishnan, and Kenneth Sultzbaugh.” (*Id.*) According to Petitioner, while Ramachandran and Sultzbaugh have been deposed, Vladyka, a resident of

Somerset, New Jersey, “no longer works for Roche” and “has not agreed to produce documents or attend a deposition.” (*Id.* at 2-3.) Petitioner asserts, “upon information and belief[,] . . . Ronald Vladyka has highly relevant information in his possession that pertains to claims in the Canadian patent litigation and that is non-duplicative of the other inventors.” (*Id.* at 3.)

In order to obtain information from Vladyka, Petitioner applied for and received a “Letter of Request” from the Federal Court of Canada. (Letter of Request, ECF No. 1-5.) The letter from the Canadian court was addressed to the United States District Court for the District of New Jersey and dated November 25, 2019. (*Id.*) The Letter of Request found that “it appears necessary for the purpose of justice that witnesses residing in your jurisdiction be examined there.” (*Id.* at 5 (emphasis omitted).) As such, the letter asked this Court to cause Ronald Vladyka to sit for an examination, under oath, and answer questions on certain topics. (*Id.* at 5.) Furthermore, the letter asks this Court to name a commissioner to conduct the examination.<sup>1</sup> (*Id.*) The Letter of Request lists the following as topics for Vladyka’s examination:

1. Background and experience, including pharmaceutical formulation and clinical trials;
2. Preparation of pirfenidone formulations containing a binder;
3. Administration of pirfenidone formulations containing a binder in humans, and collection and analysis of pharmacokinetic parameters;
4. Use of pirfenidone for treating idiopathic pulmonary fibrosis;
5. Administration of capsules of pirfenidone comprising no excipients in humans, and collection and analysis of pharmacokinetic parameters;

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<sup>1</sup> While the Federal Court of Canada appears to have contemplated the appointment of a commissioner by the United States District Court for the District of New Jersey who would conduct the examination and help facilitate discovery, Petitioner does not seek such an appointment in the Application now before this Court. Compare Pet’r’s Mem. of Law with *In re Meydan Group LLC*, No. 15-02141, 2015 WL 2453757, at \*1 (D.N.J. May 21, 2015) (appointing an attorney for Meydan as a commissioner for this purpose); Meydan Mem. of Law 1 n.1, *In re Meydan Group LLC*, 15-cv-02141, ECF No. 1-14 (requesting appointment of a Meydan attorney for this purpose).

6. Physical and chemical characterizations of any interaction between pirfenidone and excipients; and
7. Study on the impact of the interaction between pirfenidone and excipients, if any, on pharmacokinetic parameters.

(*Id.* at 6-7.)

Moreover, the Federal Court of Canada requested that this Court cause Vladyka to bring and produce at the examination the following documents:

1. Vladyka's up-to-date curriculum vitae (or resume);
2. Copies of any affidavits or declarations that have been sworn by Ronald Vladyka in any matter relating to the subject-matter of '380 and '013 Patents, or corresponding foreign patents and applications, including United States Patent Nos. US 7,767,225, US 7,988,994, US 8,383,150, US 8,753,679 and Application Publication No. US 2014/242159 and European Patent No. EP 1,940,364 and Application EP 2,431,025; and
3. Copies of documents (including laboratory notebook pages, notes, memoranda, reports, data, correspondence, emails, computer files, and notes of any discussions) relating to the formulation and clinical studies described in the '380 and '013 Patents.

(*Id.* at 5-6.) The Federal Court of Canada further requested that the examination "be scheduled and taken as soon as practically possible following the issuance of the Commission and Letter of Request." (*Id.* at 7.)

Petitioner Sandoz now moves for leave to serve a subpoena seeking the discovery outlined by the Federal Court of Canada in its November 25, 2019 Letter of Request. (*See Proposed Subpoena*, ECF No. 1-7.)

## **II. LEGAL STANDARD**

Under Section 1782, "the district court in which a person resides or is found may order him to give his testimony or statement or to produce a document or other thing for use in a proceeding in a foreign or international tribunal." 28 U.S.C. § 1782(a). Section 1782 aims to "provide

efficient means of assistance to participants in international litigation in our federal courts and encouraging foreign countries by example to provide similar means of assistance to our courts.” *In re Mesa Power Group*, No. 11-270, 2013 WL 1890222, at \*4 (D.N.J. Apr. 19, 2013) (citing *Schmitz v. Bernstein, Leibhard & Lifshitz, LLP*, 376 F.3d 79, 84 (2d Cir. 2004)). A district court is authorized to grant an application under Section 1782 if the following three prima facie statutory requirements are met: 1) the person from whom discovery is sought resides or is found within the district; 2) the discovery is for use in a proceeding before a foreign or international tribunal; and 3) the application is made by a foreign or international tribunal or any interested person. *In re Bayer AG*, 146 F.3d 188, 193 (3d Cir. 1998).

If the prima facie statutory requirements are met, a district court may, in its discretion, grant the application. *Mesa*, 2013 WL 1890222, at \*7 (stating that “a district court is not required to grant a Section 1782(a) application simply because it has the authority to do so” (citing *Intel Corp. v. Advanced Micro Devices, Inc.*, 542 U.S. 241, 264 (2004))). The Supreme Court has identified four discretionary factors that the district court should consider when ruling on a Section 1782(a) request:

1. whether ‘the person from whom discovery is sought is a participant in the foreign proceeding,’ and thus ‘the need for § 1782(a) aid generally is not as apparent as it ordinarily is when evidence is sought from a nonparticipant in the matter arising abroad’;
2. ‘the nature of the foreign tribunal, the character of the proceedings underway abroad, and the receptivity of the foreign government or the court or agency abroad to U.S. federal-court judicial assistance’;
3. ‘whether the § 1782(a) request conceals an attempt to circumvent foreign proof gathering restrictions or other policies of a foreign country or the United States’;
4. whether the request is ‘unduly intrusive or burdensome’

*In re Biomet Orthopaedics Switzerland GmBh*, 742 F. App'x 690, 696 (3d Cir. 2018) (quoting *Intel*, 542 U.S. at 247).

### **III. DISCUSSION**

#### **A. Statutory Factors**

The Court finds that Petitioner's Application satisfies all the statutory requirements. First, Petitioner has represented that Vladyka is a resident of Somerset, New Jersey. (Pet'r's Mem. of Law 2.) Courts have found that such a representation satisfies the first statutory factor. *See, e.g., In re Klein-Bentsur*, No. 18-17218, 2019 WL650874, at \*3 (D.N.J. Feb. 2, 2019). Additionally, the Federal Court of Canada has found that Vladyka resides in New Jersey. (Letter of Request 5.) Second, the discovery sought is for use in a proceeding before the Federal Court of Canada, which constitutes a foreign tribunal under Section 1782. *See John Deere Ltd. v. Sperry Corp.*, 754 F.2d 132, 134 (3d Cir. 1985) (holding that, under Section 1782, there is "little question as to the propriety of honoring [a] request for assistance" from the Federal Court of Canada). Finally, Petitioner is a party in the Canadian patent litigations and, therefore, qualifies as an interested person under Section 1782. *Intel*, 542 U.S. at 256 ("No doubt litigants are included among, and may be the most common example of, the 'interested person[s]' who may invoke Section 1782.").

#### **B. Discretionary Factors**

##### **1. Jurisdictional Reach of the Foreign Tribunal**

Vladyka is not a participant in the Canadian patent disputes. (Letter of Request 2 ("Roche is seeking, inter alia, declarations that the asserted claims of the respective patents would be infringed by Sandoz."); Pet'r's Mem. of Law at 6.) Accordingly, because Vladyka is not a participant in these proceedings, this factor weighs in favor of granting Petitioner Sandoz's Application. *Intel*, 542 U.S. at 264 (finding that "nonparticipants in the foreign proceeding may

be outside the foreign tribunal's jurisdictional reach; hence, their evidence, available in the United States, may be unobtainable absent Section 1782(a) aid.'').

## 2. Nature and Receptivity of Foreign Tribunal

Under the second discretionary factor:

a court presented with a Section 1782(a) request may take into account the nature of the foreign tribunal, the character of the proceedings underway abroad, and the receptivity of the foreign government or the court or agency abroad to U.S. federal-court judicial assistance.

*Id.* Here, the Federal Court of Canada is receptive to United States Federal court judicial assistance. (See Letter of Request 5 (requesting assistance from the United States District Court for the District of New Jersey in obtaining discovery from Vladyka).) "The Canadian court's order authorizing issuance of the subpoena demonstrates . . . that the Canadian court would be receptive to an order from this Court." *In re Ex Parte Digital Shape Techs. Inc.*, No. 16-80150, 2016 WL 3913670, at \*3 (N.D. Cal. July 20, 2016). Accordingly, this factor weighs in favor of granting Petitioner Sandoz's Application.

## 3. Attempt to Circumvent Foreign Proof-Gathering Restrictions and Policies

The third discretionary factor looks at "whether the Section 1782(a) request conceals an attempt to circumvent foreign proof-gathering restrictions or other policies of a foreign country or the United States." *Intel*, 542 U.S. at 265. There is nothing in the record before the Court evincing an effort to circumvent the foreign tribunal's proof-gathering restrictions. On the contrary, the Letter of Request addressed to this Court from the Federal Court of Canada suggests that Petitioner's request is supported by the foreign tribunal's proof-gathering procedures. *Cf. Digital Shape Techs., Inc.*, 2016 WL 3913670, at \*3 ("The Canadian court's order authorizing issuance of the subpoena demonstrates that the request is not an attempt to circumvent proof-gathering

restrictions in either Canada or the United States”). Accordingly, the third factor weighs in favor of granting Petitioner’s Application.

4. Unduly Intrusive or Burdensome Request

Under the final discretionary factor, the Court must consider whether the discovery sought is unduly intrusive or burdensome. Petitioner’s proposed subpoena does not appear to be unduly intrusive or burdensome. The deposition topics and documents requested in the proposed subpoena appear to be narrowly tailored to the subject matter of the patent disputes now pending in the Federal Court of Canada. *Cf. Mesa*, 2013 WL 1890222, at \*8 (“Mesa Power is seeking several broad-based discovery requests that must be modified.”). Furthermore, the topics and documents listed in the proposed subpoena closely track those expressly requested of this Court by the Federal Court of Canada in its November 25, 2019 letter. The Letter of Request from the very tribunal adjudicating the foreign proceeding thus supports Petitioner’s argument that the scope of the request is not unduly intrusive. Nevertheless, because Petitioner made this application *ex parte*, the Court is without sufficient information to evaluate whether the discovery it seeks is unduly burdensome to Vladyka. Once Petitioner serves the requested subpoena, Vladyka will have the opportunity to seek an order from this Court modifying or quashing the subpoena. *In the Matter of HES (Caribbean) Int’l Holdings*, No. 20-506, 2020 WL 728892, at \*4 (D.N.J. Feb. 11, 2020). The Court, therefore, finds that this factor weighs in favor of granting Petitioner’s Application.

IV. CONCLUSION

Having considered Sandoz's Application and for the reasons set forth above, the Application is granted.

  
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MICHAEL A. SHIPP  
UNITED STATES DISTRICT JUDGE